March 31, 2026

Sanhe Meditech Co.,LTD.
% Ray Wang
General Manager
Beijing Believe-Med Technology Service Co., Ltd.
Contact Address

Re: K260375
Trade/Device Name: Nd: YAG Laser Therapy Systems
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: February 5, 2026
Received: February 5, 2026

Dear Ray Wang:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

TANISHA L. HITHE -S

Digitally signed by TANISHA L. HITHE -S
Date: 2026.03.31 19:10:06 -04'00'

Tanisha L. Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
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Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260375

Device Name
Nd: YAG Laser Therapy Systems

Indications for Use *(Describe)*
The Nd: YAG Laser Therapy Systems is intended for use in tattoo removal, treatment of benign vascular lesions, treatment of benign pigmented lesions, incision, excision, ablation, vaporization of soft tissue for general dermatology, as follows:

532nm wavelength:
- Removal of light ink (red, sky blue, green, purple, and orange) tattoo.
- Treatment of benign vascular lesions including, but not limited to: telangiectasias.
- Treatment of benign epidermal pigmented lesions including, but not limited to: cafe-au-lait, solar lentiginos, senile lentiginos, Becher's, nevi, freckles, Nevus spilus, Seborrheic Keratoses.
- Treatment of Post Inflammatory Hyper-Pigmentation.

1064nm wavelength:
- Removal dark ink (black, blue and brown) tattoo.
- Removal of benign dermal pigmented lesions including, but not limited to: Nevus of Ota, Common Nevi, and Melasma.
- Removal or lightening of unwanted hair with or without adjuvant preparation.
- Skin resurfacing procedures for the treatment of acne scars and wrinkles.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

The assigned 510(k) Number: K260375

510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

1. Date of Preparation:02/03/2026

2. Sponsor Identification

SANHE MEDITECH CO.,LTD.

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3. Designated Submission Correspondent

Mr. Ray Wang

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4. Identification of Proposed Device

Trade Name: Nd: YAG Laser Therapy Systems
Common Name: Powered Laser Surgical Instrument
Model(s): GL022

Regulatory Information:
Classification Name: Powered Laser Surgical Instrument
Classification: II;
Product Code: GEX;
Regulation Number: 21 CFR 878.4810;
Review Panel: General & Plastic Surgery;

5. Identification of Predicate Device(s)

Predicate Device

510(k) Number: K202758

Product Name: Nd: YAG Laser Therapy Systems HM-YL900

Manufacturer: Shangdong Huamei Technology Co., Ltd.

Reference Device
510(k) Number: K200525
Product Name: Nd:Yag Laser Therapy Systems
Manufacturer:Beijing Kes Biology Technology Co., Ltd.

6. Device Description:

The design and production of the Nd: YAG Laser Therapy Systems fully comply with the relevant national safety standards and quality standards for laser medical equipment testing requirements, and has reached the international advanced level. This machine adopts advanced optical technology and accessories. A multifunctional microcomputer can control and adjust the size of the laser spot,making it suitable for treating diseases in different parts of the body.

The Nd: YAG Laser Therapy Systems is a kind of laser pigment treatment instrument. It uses the principle of "photo-blasting". The laser emits high energy instantaneously, causing the pigment particles to absorb the laser energy and rapidly expand and rupture. Part of the pigment is broken down into smaller particles and excreted from the body, and the other part is swallowed by human macrophages and excreted through the lymphatic system.

7. Indication For Use Statement:

The Nd: YAG Laser Therapy Systems is intended for use in tattoo removal, treatment of benign vascular lesions, treatment of benign pigmented lesions, incision, excision, ablation, vaporization of soft tissue for general dermatology ,as follows:

532nm wavelength:

● Removal of light ink (red, sky blue, green, purple, and orange) tattoo.

● Treatment of benign vascular lesions including, but not limited to: telangiectasias.

● Treatment of benign epidermal pigmented lesions including, but not limited to: cafe-au-lait, solar lentiginos, senile lentiginos, Becher's, nevi, freckles, Nevus spilus, Seborrheic Keratoses.

● Treatment of Post Inflammatory Hyper-Pigmentation.

1064nm wavelength:

● Removal dark ink (black, blue and brown) tattoo.

● Removal of benign dermal pigmented lesions including, but not limited to: Nevus of Ota, Common Nevi, and Melasma.

● Removal or lightening of unwanted hair with or without adjuvant preparation.

● Skin resurfacing procedures for the treatment of acne scars and wrinkles.

8. Substantially Equivalent (SE) Comparison

Table 8-1 General Comparison

Item	**Proposed Device**	**Predicate Device K202758**	**Reference Device K193477**	**Remark**
Device Name	Nd: YAG Laser Therapy Systems	Nd: YAG Laser Therapy Systems	Nd:Yag Laser Therapy Systems	/
Classification Regulation	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	SAME
Classification Panel	General & Plastic Surgery	General & Plastic Surgery	General & Plastic Surgery	SAME
Class	II	II	II	SAME
Product Code	GEX	GEX	GEX	SAME
Where used	Hospital	Hospital	Hospital	SAME
Indication for use	The Nd: YAG Laser Therapy Systems is intended for use in tattoo removal, treatment of benign vascular lesions, treatment of benign pigmented lesions, incision, excision, ablation, vaporization of soft tissue for general dermatology ,as follows: 532nm wavelength: ● Removal of light ink (red, sky blue, green, purple, and	The Nd: YAG Laser Therapy Systems is intended for use in tattoo removal,treatment of benign vascular lesions,treatment of benign pigmented lesions,incision, excision, ablation, vaporization of soft tissue for general dermatology as follows: 532nm wavelength: ●Removal of light ink (red, sky blue, green,	The device is indicated for the incision, excision, ablation, vaporization of soft tissues for general dermatology, dermatologic and general surgical procedures for coagulation and hemostasis. 532nm wavelength: -Tattoo removal: light ink(red, tan, purple, orange, skyblue, green) -Removal of Epidermal	SAME

	orange) tattoo. ● Treatment of benign vascular lesions including, but not limited to: telangiectasias. ● Treatment of benign epidermal pigmented lesions including, but not limited to: cafe-au-lait, solar lentiginos, senile lentiginos, Becher's, nevi, freckles, Nevus spilus, Seborrheic Keratoses. ● Treatment of Post Inflammatory Hyper-Pigmentation. 1064nm wavelength: ● Removal dark ink (black, blue and brown) tattoo. ● Removal of benign dermal pigmented lesions including, but not limited to: Nevus of Ota, Common Nevi, and Melasma. ● Removal or lightening of unwanted hair with or without adjuvant preparation. ● Skin resurfacing procedures for the treatment of acne scars and wrinkles.	purple, and orange) Tattoo. Treatment of benign vascular lesions including, but not limited to: telangiectasias. ●Treatment of benign epidermal pigmented lesions including, but not limited to: cafe-au-lait, solar lentiginos, senile lentiginos, Becher's, nevi Freckles, Nevus spilus, Seborrheic Keratoses. ●Treatment of Post Inflammatory Hyper Pigmentation. 1064nm wavelength: ●Removal dark ink (black, blue and brown) tattoo. ●Removal of benign dermal pigmented lesions including, but not limited to: Nevus of OTA, Common Nevi, and Melasma, ●Removal or lightening of unwanted hair with or without adjuvant preparation ●Skin resurfacing procedures for the treatment of acne scars and wrinkles.	Benign Pigmented Lesions -Removal of Minor Benign Vascular Lesions including but not limited to telangiectasias -Treatment of Lentigines -Treatment of Cafe-Au-Lait -Treatment of Seborrheic Keratoses -Treatment of Post Inflammatory Hyper-Pigmentation -Treatment of Becker's Nevi, Freckles and Nevi Spilus 1064nm Wavelength: -Tattoo removal: dark ink (black, blue and brown) -Removal of Nevus of Ota -Removal or lightening of unwanted hair with or without adjuvant preparation. -Treatment of Common Nevi -Skin resurfacing procedures for the treatment of acne scars and wrinkle	

Table 8-2 Performance Comparison

ITEM	Proposed Device	Predicate Device K202758	Reference Device K193477	Remark
Laser Type	Nd: YAG	Nd: YAG	Nd: YAG	SAME
Laser Classification	Class IV	Class IV	Class IV	SAME

Laser Wavelength	1064nm 532nm	1064nm 532nm	1064nm 532nm	SAME
Aiming Beam Wavelength	650nm	650nm	635nm	Similar
Output energy	1200mJ for 1064nm 500mJ for 532nm	1000mj for 1064nm 500mj for 532nm	1600mj for 1064nm 400mj for 532nm	Similar
Fluence	1.26-32.96J/cm^2 for 1064nm 0.56-13.78J/cm^2 for 532nm	1.27-31.8 J/cm^2 for 1064nm 0.6 - 15.9 J/cm^2 for 532nm	1064nm 0.4-51.0 J/cm^2 532nm 0.4-12.7 J/cm^2	Similar
Spot Size	2-10mm	2-10mm	2-10mm	SAME
Frequency	1-10Hz	10 Hz Max	1-6 Hz Max	SAME
Pulse Duration	5-10ns	4-6ns	5-10ns	Different

Analysis：

Similar - Output energy and Fluence

The proposed device has similar Output energy and Fluence from the predicate device and Reference Device.

For the difference on output energy and fluence between the predicate and proposed device, the safety of the product is no problem.And the proposed device has passed the IEC60601-1 test, IEC60601-1-2 test, IEC60601-2-22 test, IEC60825-1 test and performance test, the safety and performance of the product can be ensured.

Different - Pulse Duration

The proposed device has different pulse duration from the predicate device.

For the difference on pulse duration between the predicate and proposed device(s), we can see that the pulse duration range of proposed device is same as the Reference Device. The pulse duration between the proposed device and the predicate device only with minor difference. And we think this minor difference will not affect the effectiveness and safety. And the proposed device has passed the IEC60601-1 test, IEC60601-1-2 test, IEC60601-2-22 test, IEC60825-1 test and performance test, the safety and performance of the product can be ensured.

Table 8-3 Safety Comparison

Item	**Proposed Device**	**Predicate Device K202758**	**Remark**
EMC, Electrical and Laser Safety			
Electrical Safety	Comply with IEC 60601-1, IEC 60601-2-22	Comply with IEC 60601-1, IEC 60601-2-22	SAME
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	SAME

Laser Safety	Comply with IEC 60601-2-22, IEC 60825	Comply with IEC 60601-2-22, IEC 60825	SAME

9. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- IEC 60601-1 Edition 3.2 2020-08, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Edition 4.1 2020-09, Medical Electrical Equipment-Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility-Requirements And Tests
- IEC 60825-1:2014, Safety of laser products - Part 1: Equipment classification, and requirements
- IEC 60601-2-22: 2012 Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
- ISO 10993-5: 2009 Biological Evaluation of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-10 Fourth edition 2021, Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- ISO 10993-23 First edition 2021-01, Biological evaluation of medical devices - Part 23: Tests for irritation

10. Clinical Test Conclusion

No clinical study is included in this submission.

11. Substantially Equivalent (SE) Conclusion

Based on the nonclinical tests performed, the subject device is as safe, as effective, and performs as well as the legally marketed predicate device, Multi-Modality Workstation cleared under K202758.